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**Please find below and/or attached an Office communication concerning this application or proceeding.**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/618,223  
Filing Date: July 11, 2003  
Appellant(s): MANGIARDI ET AL.

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Trent A. Kirk  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 8 June 2009 appealing from the Office action mailed 14 October 2008.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is deficient. 37 CFR 41.37(c)(1)(v) requires the summary of claimed subject matter to include: (1) a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number, and to the drawing, if any, by reference characters and (2) for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function

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and step plus function as permitted by 35 U.S.C. 112, sixth paragraph, must be identified and the structure, material, or acts described in the specification as corresponding to each claimed function must be set forth with reference to the specification by page and line number, and to the drawing, if any, by reference characters. The brief is deficient because citations to Figures 14-18 and text corresponding to the embodiment of Figures 14-18 is not relevant to the claimed embodiment, as the limitation of "wherein the inward facing surfaces of the legs are in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit" (claims 1, 7, 24 and 37) is only supported by the embodiment of Figures 1-13 (see Figures 9 and 12 and Applicant's specification page 9 lines 16-17) and not by the embodiment of Figures 14-18 (see page 10 lines 23-26 describing the legs as "adjacent" instead of "flush").

#### **(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

#### **(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

5919147	JAIN	6-1999
5010892	COLVIN ET AL.	4-1991
6712771	HADDOCK ET AL.	5-2004
6033359	DOI	5-2000
6450977	BAXTER-JONES	11-2002
4972584	BAUMANN	11-1990

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 5, 12 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Independent claims 1, 7 and 37 recite that the inward facing surfaces of the legs are in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit. Claims 5, 12 and 41 recite that the distal ends of the legs are coupled together as shown in the embodiment of figures 14-18. The original disclosure states, "when the legs are constrained by the exterior conduit 130 they lay substantially flush with respect to one another" (page 9, lines 16-17). However, this

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statement pertains to the embodiment of figures 1-13 when the distal ends of the legs are not coupled together. Regarding the embodiment of figures 14-18, the original disclosure states, "when the measurement assembly is retracted, the legs are relaxed and reside adjacent one another so that the legs may be retracted within the exterior conduit" (page 10, lines 23-26). However, the original disclosure does not appear to support inward facing surfaces of the legs in the embodiment of figures 14-18 being in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit.

Therefore, the subject matter of claims 5, 12 and 41 does not appear to be properly supported by the original disclosure.

Claims 1, 3-8, 10-24, 37, 39-42, 45, 48, 52 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain (US 5,919,147) in view of Colvin et al. (US 5,010,892), Haddock et al. (US 6,712,771), Doi (US 6,033,359), and Baxter-Jones (US 6,450,977).

Jain teaches a body lumen measuring device for measuring a target segment of a lumen of a patient so as to select a suitable interventional prosthesis. The device (10) includes an exterior conduit (22); an interior conduit (24) slidably disposed within the exterior conduit and having a depth marking mechanism (42); a measurement assembly (26 or 54) including a plurality of legs (44 or 56, 58) coupled with each other proximal the distal ends thereof and coupled about the distal end of the interior conduit; and a handle (24, 30) operatively connected with the measurement assembly. The handle

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includes means for opening and closing the measurement assembly by actuating the handle along a continuum between a first closed configuration and a second open configuration. The inward facing surfaces along a portion of the legs are in flush contact with one another along a portion distal of the proximal ends when the measurement assembly is closed within the exterior conduit (see figure 2). The legs form an acute angle with respect to one another as the measurement assembly is moved distally in relation to the first conduit (see figures 3 and 6). In an alternative embodiment, the distal ends of the legs are coupled together (see figures 5 and 6). The handle further includes the measurement indicator, wherein target lumen dimensions are calculated based on the relative distance the handle travels along the continuum between the first and second handle locations (column 1, lines 45-47). The device is used to measure a target segment of a lumen of a patient so as to select a suitable interventional prosthesis (column 1, lines 16-20). In operation, the device is introduced into an appropriate anatomical orifice of a patient; delivered adjacent a target segment of a lumen within the patient; and the diameter of the target segment is measured within the patient (paragraph bridging columns 3 and 4). The device further comprises an optical scope to view placement of the measurement assembly (column 3, lines 57-58).

Jain teaches all of the limitations of the claims except that the exterior conduit has measurement markers formed on a portion thereof, that the depth markings on the interior conduit are visible through the exterior conduit, measuring length of a target segment, measuring dimensions of a stenotic segment, that the inward facing surfaces of the legs are in flush contact with one another from the distal ends of the legs to the

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proximal ends of the legs when the measurement assembly is closed within the exterior conduit, that the lumen facing surface of each of the legs includes a plurality of measurement markers, and that the exterior conduit is configured to engage the measurement markers.

Colvin et al. teach a body lumen measuring device that is capable of allowing a user to calculate the length and diameter of a suitable interventional prosthesis as well as the height and length of stenosis during the same exploratory procedure. The device (10) includes an exterior conduit (12) having measurement markers (24) formed on a portion thereof; an interior conduit (16) slidably disposed within the exterior conduit and having a depth marking mechanism (22) which may be visible through a portion of the exterior conduit (20); a measurement assembly including a plurality of legs (54a-54c) coupled with each other proximal the distal ends thereof and coupled about the distal end of the interior conduit; and a handle (14) operatively connected with the measurement assembly. The handle includes means for opening and closing the measurement assembly (18) by actuating the handle along a continuum between a first closed configuration and a second open configuration. An optical endoscope may be operatively coupled therewith, so that the measuring step may be accomplished using the optical endoscope. The device may be used to measure the diameter and length of a target segment of the lumen within the patient, including the height and length of the stenosis (column 3, lines 65-66).

Applicant has not disclosed that using a measurement indicator arrangement having a plurality of measurement markers formed on a portion of the exterior conduit

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and a depth marking mechanism on the interior conduit that is visible through a portion of the exterior conduit solves any stated problem or is for any particular purpose.

Moreover, it appears that the measurement indicator arrangement of Jain, or applicant's invention, would perform equally well with the plurality of measurement markers formed on a portion of the exterior conduit and a depth marking mechanism on the interior conduit that is visible through a portion of the exterior conduit, similar to the arrangement taught by Colvin et al. Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified Jain to include a measurement indicator arrangement similar to that of Colvin et al., because such a modification would have been considered a mere design consideration which fails to patentably distinguish over Jain.

As noted above, Colvin et al. teach measuring height and length of body lumens including that of stenotic lumens to facilitate accurate sizing of a device to be placed in the lumen. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have measured the length of a target lumen and height and length of stenoses as taught by Colvin et al. in the method of Jain in order to obtain additional information about the proper size of a device to be inserted into a body lumen.

Haddock et al. disclose legs (302 in figures 3A-B or 310 in figure 3C) of a measurement assembly, wherein inward facing surfaces of the legs are in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within an exterior conduit (300). The flush legs of

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Haddock et al. would be advantageous since relative movement of the legs would be prevented when the legs are stored within the exterior conduit. Thus, potential damage to the legs would be avoided before the device is used. Furthermore, one of ordinary skill in the art would recognize that allowing the legs to be closed in flush contact along their entire lengths would allow the diameter of the conduit to be reduced allowing access to smaller lumens in the body. It would have been obvious to one having ordinary skill in the art at the time of invention to have modified the legs of Jain as modified by Colvin et al. so that the legs are in flush contact along their entire lengths when the measurement assembly is closed within an exterior conduit as taught by Haddock et al. in order to prevent relative movement and damage to the legs before the legs are extended from the exterior conduit and to reduce the overall diameter of the conduit so that smaller body lumens can be accessed by the device.

Doi teaches a plurality of measurement markers (8) on the lumen facing surfaces of legs (3) that are capable of providing information regarding the diameter of the target segment using an optical system (column 3, lines 48-52). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have made a plurality of measurements markers on each leg of Jain as modified by Colvin et al. and Haddock et al. as taught by Doi in order to achieve the predictable result of providing appropriate markers on a measurement tool to obtain measurements within a patient.

Baxter-Jones teaches a lip that extends from the distal end of an exterior conduit (1116) to engage detents (1130) defined in an elongated measurement member (1108).

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Since the exterior conduit (1116) is flexible, the exterior conduit will temporarily form a lip when slid over the detents. Baxter Jones teaches incorporating the detents with measurement markings for the purpose of locking the elongated measurement member (1108) with the exterior conduit (1116).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a lip that engages detents as taught by Baxter-Jones in the device of Jain as modified by Colvin et al., Haddock et al. and Doi in order to achieve the predictable result of releasably locking the legs with the exterior conduit.

Claims 46, 49, 50, 53, 54 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain as combined with Colvin et al., Haddock et al., Doi, and Baxter-Jones as applied to claims 1, 3-8, 10-24, 37, 39-42, 45, 48, 52 and 56 above, and further in view of Baumann (US 4972584).

Jain as combined with Colvin et al., Haddock et al., Doi, and Baxter-Jones teach the devices of claims 45 and 56 and the methods of claims 48 and 52. Jain as combined with Colvin et al., Haddock et al., Doi, and Baxter-Jones do not teach that the distal end of the exterior conduit comprises a lip protruding from the inner surface that is configured to engage the detents. Baumann teaches an exterior conduit (54) comprising inner and outer surfaces, and wherein the distal end of the exterior conduit comprises a lip (46 in Figure 3 or 57 in Figure 6 or 7) protruding from the inner surface that is configured to engage detents (49), and measuring by displacing the exterior conduit and measurement assembly (49a on 11) relative to one another such that the lip

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engages a detent (Figure 6). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the lip protruding from the inner surface that is configured to engage the detents as taught by Baumann in the invention of Jain as modified by Colvin et al., Haddock et al., Doi, and Baxter-Jones to provide for easily repeatable measurements among various users, without the need for estimating how far between two detents or measurements the device is. As combined with Jain as modified by Colvin et al., Haddock et al., Doi, and Baxter-Jones, the lip would engage the detents defined in the legs.

#### **(10) Response to Argument**

Regarding Applicant's arguments regarding the 35 USC 112 first paragraph rejections of claims 5, 12 and 41, the Examiner notes that the embodiment of Figures 1-13 is disclosed as having legs "that lay substantially flush with respect to one another" when constrained by the exterior conduit (page 9 lines 15-18). However, with regards to the embodiment of Figures 14-18, the Applicant disclosed that "the legs are relaxed and reside adjacent one another so that the legs may be retracted within the exterior conduit" (page 10 lines 23-26). The Examiner notes that "adjacent" does not define the same spatial limitations as "substantially flush with", and as these different terms were used to describe different embodiments, one can not presume that the flush contact in the first embodiment is implied in the second embodiment. With respect to Applicant's arguments regarding the similarity of Figures 4 and 15, the Examiner notes that Figures 4 and 15 do not show how the legs relate to each other in the retracted state, and that

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Applicant's Figure 9 clearly shows the legs of the embodiment of Figures 1-13 in flush contact while Applicant did not provide a similar figure for the embodiment of Figures 14-18. In regards to the comments regarding Figure 18, it is respectfully submitted that one would need to see a cross-sectional view of the second embodiment in the closed configuration to determine if the legs are in flush contact.

Regarding Applicant's arguments that there is not a motivation to combine Haddock et al. with the Jain reference, the Examiner notes that both references contain structures that expand inside a tubular member to contact the tubular member and measure some aspect of the tubular member. As such, one of ordinary skill in the art would look towards structures that expand from an exterior conduit to contact tubular structures when looking to measure tubular structures.

In response to Applicant's argument that Baxter-Jones is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Baxter-Jones is a measuring devices for measuring parts of the body.

Regarding Applicant's arguments that Jain and Doi do not disclose an exterior conduit that is configured to engage measurement markers defined on the lumen-facing surfaces of a plurality of legs, the Examiner notes that all the references, as combined, teach this limitation. The Examiner further notes that Doi's markers are not limited to being painted on, as Doi states "The scale 8 can be formed, for example, by painting

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lines in a cylindrical manner on the outer surface of the flexible tube 1.... However, the scale 8 may be modified in various manners depending on the intended use of the length-measuring tool." (Doi Column 3 lines 12-14 and 16-18) The Examiner notes that one having ordinary skill in the art at the time the invention was made would have known that measurements markers can be painted on, carved into, or projected from a measurement tool, as is known for producing a ruler. Further, Doi was cited for teaching measurement markers on the lumen facing surfaces of legs; Baxter-Jones was cited for teaching an exterior conduit that is configured to engage measurement markers, and the measurement markers of Baxter-Jones are capable of being engaged.

In response to Applicant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Regarding Applicant's arguments that claims 45, 48, 52 and 56 require indentations because of the claim language "the measurement markers of the legs comprise detents defined therein", the Examiner disagrees. The Examiner notes that Baxter-Jones uses "unidirectional detent 1130b" (Column 19 line 41) to describe the projections of Figure 12b as cited above, and that the dictionary (Merriam Webster's

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Collegiate Dictionary Tenth Edition Copyright 1997 page 1223) defines "therein" as "1. in that place 2. In that circumstance or respect". Therefore, the claim was not interpreted as requiring measurement markers "carved into the legs so as to form detent or lip catches" (Applicant's 8 June 2009 Supplemental Appeal Brief, page 16, the sixth line of the second paragraph, quoting Applicant's specification, page 10 lines 5-6) as this was not the language claimed. Further, the Examiner notes that Baxter-Jones teaches measurement markers comprising detents, and, as combined with the device of Jain as modified by Colvin et al., Haddock et al. and Doi, these detents would be on the legs.

In response to applicant's argument that Baumann is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Baumann is analogous art as it is part of the art of measurement devices.

Regarding Applicant's arguments that the detents of Baxter-Jones could not be used with the lip of Baumann, the Examiner notes that one of ordinary skill in the art at the time the invention was made would have known to substitute the detents (notches 49 Figures 6 and 7) of Baumann for the projection-type detents of Baxter-Jones.

Regarding Applicant's arguments that Baumann does not teach that the end of an exterior conduit comprises a lip protruding from the inner surface that is configured to engage detents, the Examiner disagrees. The Examiner notes that Baumann teaches

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an exterior conduit (54) comprising inner and outer surfaces, wherein the distal end of the exterior conduit comprises a lip (46 in Figure 3 or 57 in Figure 6 or 7) protruding from the inner surface that is configured to engage detents (49). The Examiner notes that element 46 and outer end 57 both protrude from the inner surface. The Examiner further notes that dictionary definitions of lip include “projecting part” and that elements 46 and 57 of Baumann are projecting parts.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner’s answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Emily Lloyd

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